

REMARKS

Reconsideration in light of the foregoing amendments and remarks that follow is respectfully requested.

Claims 1-4, 7-11, 16-19, and 21 are pending. Claims 7-9, 11, 18 and 19 are withdrawn from consideration by the Examiner pursuant 37 CFR 1.142(b) as drawn to a non-elected invention. Claim 1 has been amend to address points raised by the Examiner in the outstanding Office Action.

Claims 1-4, 10, 16, 17, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of complement activation by sCR1, does not provide enablement for several inhibitors recited in the claims. Applicants respectfully traverse.

Though the claims have not been limited to "sCR1", the claims have been limited, in part, to address some of the Examiner's concerns. As amended, the claims recite known complement activation inhibitors and are limited to hypersensitivity treatment where the hypersensitivity is due to specific amphiphilic carriers- polyethoxylated oil or a derivitized polyethoxylated oil. The practice of the invention merely requires the selection of "complement activation inhibitor" from the claimed list and their use. This may require some routine experimentation. It certainly does not require undue experimentation.. In any event, the outstanding Office Action does not establish the presence of "undue" experimentation relative to the invention as claimed. Examples showing successful operation of the invention are provided to further guide the artisan of ordinary skill in the practice of the invention as claimed.

In the absence of a proper prima facie case establishing the presence of "undue" experimentation, withdrawal of the rejection as to the claims, as amended, is respectfully requested.

Claims 1-4, 10, 16, 17, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse.

Claim 1 has been amended to address some of the Examiner's concerns. It is also respectfully submitted that the Examiner reconsider his position relative to "GS1", "C1qInh", and "compound K-76COOH". These compounds are all known in the art. Their meaning is clear. See for example U. S. Patents Nos. 6,166,288; 5,109,144; 5,264,549; and 5,851,528 and

Am J Physiol Heart Circ Physiol (October 7, 2005). Doi: 10.1152/ajpheart.00622.205 (J. Szebeni) (anti-C5a antibody (GS1)) .

Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1-4, 10, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lodge (5,462,726). Applicants respectfully traverse.

Applicants have considered Lodge and the teachings attributed to Lodge by the Examiner. The claims have been amended to avoid those teachings- "Indomethacin" was deleted from the claims. Lodge teaches the use of "thromboxane A2 receptor antagonists." Since Lodge no longer teaches each and every element required by the amended claims, there is no anticipation.

Withdrawal of the rejection is respectfully requested.

Claims 1-4, 6, 10, 16-17 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terwogt (Cancer Treatment Reviews, March 1997) or O'Brien (Annals of Oncology, 1992) in view of Ko (5,851,528) and applicant's statements of prior art. Applicants respectfully traverse.

The teachings of both Terwogt and O'Brien as characterized by the Examiner are noted. It is agreed that neither reference mentions complement activation inhibitors or their use. There is also no suggestion of a relationship between complement system inhibition and the alleviation of the symptoms associated with hypersensitivity.

The Examiner relies on Ko to establish a tie-in with "hypersensitivity" and the use of complement activation inhibitors to treat hypersensitivity generally. (The claims actually require more specific "tie-in"- the claimed subjects "have" hypersensitivity caused by specific compounds and are treatment using specific complement activation inhibitors.) Ko's teachings in this regard appear to be incomplete in that regard as to the amended claimed method. Ko does not mention Cremophors. Ko does not mention the treatment of hypersensitivity caused by Cremophors. Ko does not mention the claimed complement activation inhibitors. Ko does not convey a reasonable expectation that the use of complement activation inhibitors, generally, would alleviate hypersensitivity symptoms caused by the claimed compounds. Rather, Ko deals with specific hybrid peptides and demonstrates their activity in a specific setting. There is not even a showing that demonstrated alleviation of hypersensitivity symptoms, caused by the claimed compounds, using the taught hybrid peptides.

Further, the unexpected nature of Applicants' discovery should be appreciated from a "fair" reading of the instant specification, which suggests that at the time the application was filed there was a high degree of uncertainty and unpredictability in this technical area, especially, in terms of the cause of the hypersensitivity by Cremophors and paclitaxel and also as to the suitability of claimed complement activation inhibitors to alleviate Cremophor induced hypersensitivity symptoms.

It is respectfully submitted that a proper prima facie case of obviousness has not been established. Withdrawal of the rejection is respectfully requested.

Claims 1-4, 6, 10 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terwogt (Cancer Treatment Reviews, March 1997) or Lodge, cited above, further in view of Wheeler (5,478,860). Applicants respectfully traverse.

The deficiencies of Lodge and Terwogt are noted above.

Wheeler does not remedy these deficiencies. Wheeler is characterized as teaching that Cremophor can produce acute toxic side effects- "hypersensitivity." Wheeler is further characterized as suggesting the use of anti-inflammatory agents to treat these side effects. There is no mention of complement activation inhibitors, especially like those claimed and/or their use to treat hypersensitivity.

Withdrawal of the rejection is respectfully requested; a proper prima facie case has not been established.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lodge cited above. Applicants respectfully traverse.

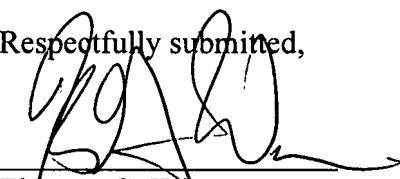
It is noted that the specific thromboxane A2 receptor antagonist, "Indomethacin", identified by the Examiner as taught by Lodge has been deleted from the claims. Lodge's relevancy as to the amended claims appears lost. The claims are not directed to the use of thromboxane A2 receptor antagonists. Rather, the claims are directed to the use of specific complement activation inhibitors. The other references of record do not provide an equivalency teaching relative to Lodge's antagonists and complement activation inhibitors.

The teachings are insufficient to establish a proper prima facie case of obviousness.

Accordingly, withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, the application is believed to be in condition for allowance and a notice to that effect is respectfully requested.

Should the Examiner not agree that the Application to be in allowable condition or believe that a conference would be of value in expediting the prosecution of the Application, Applicants request that the Examiner telephone undersigned Counsel to discuss the case and afford Applicants an opportunity to submit any Supplemental Amendment that might advance prosecution and place the Application in allowable condition.

Respectfully submitted,

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